00-74948

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

VICTORIA A. ROBERTS

MAGISTRATE JUDGE MORGAN

REBECCA BENNISH and ALICE OLSTEIN, individually and on behalf of all others similarly situated,

Plaintiffs,

BARR LABORATORIES, INC.; ZENECA, INC.; and ASTRAZENECA INC.,

Defendants.

Case No.:

CLASS ACTION

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs, on behalf of themselves and all others similarly situated, for their complaint against defendants Barr Laboratories, Inc., Zeneca, Inc. and AstraZeneca Inc., upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, allege as follows:

NATURE OF THE ACTION

1. The most common malignancy to affect women is breast cancer, which remains one of the leading causes of death among women. The most essential drug for treatment for breast cancer is tamoxifen citrate ("tamoxifen"). In the United States, the only tamoxifen available on the market is manufactured by Defendant Zeneca, Inc. and/or its successor (as a result of a 1999 merger) AstraZeneca, Inc. (collectively "Zeneca"). This drug is sold by Zeneca under the brand-name Nolvadex®. Zeneca's tamoxifen also is sold in the United States as a "generic" by Defendant Barr Laboratories, Inc. ("Barr"), a generic manufacturer, pursuant to an illegal and anti-competitive arrangement between Zeneca and Barr that precludes the marketing of competing generic versions of tamoxifen.

2. On April 20, 1992, following a trial on the merits, the patent for tamoxifen was found to be **unenforceable**. *Imperial Chem. Ind., PLC v. Barr Lab., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992). While an appeal from that judgment was pending in the Federal Circuit, agreements were reached by which Barr agreed to abandon its challenge to the tamoxifen patent and to ***not*** manufacture and market its own generic tamoxifen until the expiration of the patent in 2002. In exchange, Zeneca and its former parent, Imperial Chemicals Industries, PLC, agreed to: (1) pay Barr *$21 million*; and (2) supply Barr with Zeneca-manufactured tamoxifen for resale as a "generic" in the United States. The agreements between Barr and Zeneca were conditioned upon the Federal Circuit directing the trial court to vacate the findings of patent invalidity, which it did. *Imperial Chemical Industries, PLC v. Heumann Pharma GmbH & Co. et al.*, 991 F.2d 811, 1993 WL 118931 (Fed.Cir. 1993) (unpublished disposition). The agreements, nonetheless, were privately negotiated without meaningful review or approval by any court.

3. As a result of the collusive agreements between Zeneca and Barr, there has not been, and is not now, competition in the market for tamoxifen. While generic drugs are usually priced 30% to 80% below the brand-name product, the "generic" tamoxifen sold by Barr is priced at only 5% less than Nolvadex®. Throughout the Class Period (defined below), women in need of tamoxifen have had no choice but to pay these supra-competitive and monopolistic prices. But for defendants' illegal agreement, lower-priced generic tamoxifen would have been available in the United States throughout the Class Period.

4. This action is brought by Plaintiffs and all other consumers who purchased tamoxifen during the Class Period in the United States and its territories (for Count I, II and Count IV) or in Michigan (for Count II) or in Arizona, California, District of Columbia, Florida, Kansas, Louisiana,

Maine, Massachusetts, Michigan, Minnesota, New Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, West Virginia, and Wisconsin (collectively the "Indirect Purchaser States") (for Count III).

5. Plaintiffs seek a judgment declaring the Confidential Settlement Agreement and Distribution and Supply Agreement (together the "Agreements"), described herein, are unlawful under Sections 1 and 2 of the Sherman Act, 15. U.S.C. §§ 1, 2, and, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of Zeneca's and Barr's anti-competitive arrangement. Unless enjoined, Defendants' unlawful conduct will continue unchecked and the Plaintiffs and the Class (as defined below) will continue to bear the financial brunt of the antitrust violations. Plaintiffs also assert claims for continuing violations of Michigan's Antitrust Reform Act, MCL § 445.771 *et seq.* (the "Antitrust Act"), the antitrust and/or consumer protection laws in the Indirect Purchaser States and for unjust enrichment. Plaintiffs and the Class they seek to represent do not seek any relief under Section 4 of the Clayton Act, 15 U.S.C. § 15.

JURISDICTION AND VENUE

6. This Complaint is filed and these proceedings are instituted under Section 16 of the Clayton Act, 15 U.S.C. § 26, to enjoin and prevent Defendants' continuing unlawful contract, combination and conspiracy in violation of §§ 1 and 2 of the Sherman Act, 15 U.S.C.§§ 1 and 2, and the resulting exclusionary, monopolistic and unlawful trade restraints that have harmed and continue to harm Plaintiffs and the Class. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) 15 U.S.C. § 22 and § 26. This Court has supplemental jurisdiction over Plaintiffs' remaining state law claims pursuant to 28 U.S.C. § 1367(a).

7. In addition, this Court has personal jurisdiction over each Defendant as co-conspirators as a result of the acts of any of the co-conspirators occurring in the United States in connection with Defendants' violations of the federal antitrust laws and Indirect Purchaser States' antitrust and/or consumer protection laws.

8. Defendants are found or transact business within this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District. A substantial part of the events or omissions giving rise to the claims occurred in this District. Venue is proper within this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

TRADE AND COMMERCE

9. At all material times, tamoxifen manufactured by Zeneca and sold by Zeneca or Barr was shipped across state lines and sold to United States customers located outside the state of manufacture.

10. During the relevant time period, in connection with the purchase and sale of tamoxifen, monies as well as contracts, bills and other forms of business communications and transactions were transmitted in a continuous and uninterrupted flow across state lines.

11. During the relevant time period, various devices were used to effectuate the conspiracy alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants as charged in this Complaint were within the flow of, and have substantially affected, interstate commerce.

THE PARTIES

12. Plaintiff Rebecca Bennish, a resident of Oak Park, Michigan, has purchased tamoxifen for her own use during the Class Period (as defined below). During the Class Period, Ms. Bennish

has, as a result of the antitrust violations alleged herein, paid supra-competitive and monopolistic prices for tamoxifen and has been deprived of the opportunity to purchase lower cost generic bioequivalents of the drug. Unless Defendants' violations of the federal antitrust laws and state antitrust and/or consumer protection laws are enjoined by the Court, Ms. Bennish will continue to be deprived of a competitive market and will be forced to continue to purchase tamoxifen at supra-competitive and monopolistic prices.

13. Plaintiff Alice Olstein, a resident of Southfield, Michigan, has purchased tamoxifen for her own use during the Class Period (as defined below). During the Class Period, Ms. Olstein has, as a result of the antitrust violations alleged herein, paid supra-competitive and monopolistic prices for tamoxifen and has been deprived of the opportunity to purchase lower cost generic bioequivalents of the drug. Unless Defendants' violations of the federal antitrust laws and state antitrust and/or consumer protection laws are enjoined by the Court, Ms. Olstein will continue to be deprived of a competitive market and will be forced to continue to purchase tamoxifen at supra-competitive and monopolistic prices.

14. Zeneca Inc. is a Delaware corporation with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. Until April 1999, Zeneca was a subsidiary of Zeneca Group PLC (UK). On April 6, 1999, Zeneca Group PLC officially merged with Astra Pharmaceuticals L.P to form AstraZeneca Inc., which is headquartered in London, UK. Zeneca researches, develops, and produces medicines for use in seven major therapeutic areas: cardiovascular, central nervous system, gastrointestinal, infection, oncology, pain control and anaesthesia, and respiratory. Reference in this Complaint to "Zeneca" includes Zeneca, Inc. prior to April 6, 1999 and Zeneca, Inc. and/or AstraZeneca, Inc. thereafter.

15. Barr is a New York corporation with its principal place of business at Two Quaker Road, Pomona, New York. Barr maintains additional facilities in New Jersey and Virginia. Barr is a developer and manufacturer of generic pharmaceutical drugs. Barr presently manufactures and markets approximately seventy generic drugs.

RELEVANT MARKET

16. As to those claims where it is required, the relevant product market is the market for the manufacture and sale of tamoxifen, including Nolvadex® and any generic bioequivalent product rated "AB" by the FDA. The relevant geographic market is the United States and its territories as a whole (for Count I and Count IV), Michigan (for Count II) and the Indirect Purchaser States (for Count III). At all relevant times, including the present, Zeneca's market share in the relevant product and geographic markets was 100%, with Barr marketing Zeneca's product as a generic. By alleging these relevant markets, Plaintiffs and the Class do not waive any allegations asserting that Defendants' conduct was a *per se* violation of the federal and state antitrust laws and consumer protection laws.

FACTUAL ALLEGATIONS

17. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. In 1997, over $97 billion of prescription drugs were dispensed in the United States alone. The sale of prescription drugs in the United States grew to approximately $103.5 billion in 1998 and is estimated to have reached $120 billion in 1999.

A. The Federal Scheme For Approval of Generic Drugs

17. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FD&C Act"), approval by the FDA is required before a company may begin selling a new drug. Premarket

approval for a new drug, often referred to as a "pioneer drug," must be sought by filing a New Drug Application with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of the patents involved, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 ("Hatch-Waxman Act"). The patents covering pioneer drugs are listed in the FDA "Orange Book."

18. Generic drugs are drugs which the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

19. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be dispensed by a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug which has been approved by the FDA is available.

20. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the

AB-rated generic at a lower price.

21. Once a physician writes a prescription for a brand-name drug such as Nolvadex®, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug. As explained on Barr's web page,

> The majority of states use the FDA's "AB" rating of therapeutic substitution as the foundation for generic substitution, either by permitting substitution based on the FDA's Orange Book listing, or by using the FDA's "AB" rating as the basis for cursory administrative approval. A total of 39 states permit substitution of generic products while 11 states mandate generic substitution.

http://www.barrlabs.com/pages/faqcon.htm.

22. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. As explained on Barr's web page,

> Generic pharmaceuticals can cost 30-80% less than the equivalent, branded product. Yet, the consumer is getting the same product, manufactured to the same high standards, as the brand name product.
>
> * * *
>
> [I]ntroduction of generic products—which offer consumers a choice—results in competition that can also help lower prices. The generic makes a real contribution to lowering health care costs, by offering the very same quality pharmaceutical products at significantly lower prices.

http://www.barrlabs.com/pages/faqcon.htm.

23. A branded drug ordinarily loses most of its market share to generic competitors less than a year after the introduction of generic competition, unless the branded manufacturer lowers prices to meet competition. Either way, consumers benefit from the choice and competition.

24. In 1984, Congress enacted the Hatch-Waxman Act to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. The Hatch-Waxman Act was *not* intended to provide a market windfall for crafty, albeit industrious, market players. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an abbreviated new drug application ("ANDA") which incorporates by reference the safety and effectiveness data developed and previously submitted by the company that manufactured the original, pioneer drug. The Hatch-Waxman Act also provides an economic incentive to the manufacturer of the first generic drug to receive approval — a 180 day statutory period of market exclusivity during which time the manufacturer has the right to market its drug free from other generic competition.

25. The most important new information that must be included in the ANDA concerns the generic company's position vis-a-vis the original patent, and the ANDA filer must make one of four certifications:

I. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

II. that the patent for the pioneer drug has expired (a "Paragraph II Certification");

III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 35b5(j)(2)(A)(vii).

26. The branded drug owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. If no action is initiated within 45 days, the process for FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.

27. Accordingly, pioneer drug patent holders need only to file a patent infringement lawsuit within 45 days of receipt of a Paragraph IV Certification in order to block an ANDA applicant's generic drug from entering the market for up to 30 months.

B. Tamoxifen

28. Breast cancer is the most common malignancy to affect women, and it remains one of the leading causes of death among women. During the 1990s, more than 1.5 million women in this country have been newly diagnosed with breast cancer, and over 25 percent of these women will ultimately die of the disease. In 1999 alone, approximately 175,000 women developed breast cancer in the United States.

29. Although the etiology of breast cancer is not yet fully understood, researchers have identified two principal risk factors (other than age) that play a role in the development of the disease. First, genetic background, including some specific gene mutations, has been shown to cause a minor percentage of breast cancer cases. The second and far more significant factor (and the one that accounts for the vast majority of breast cancers) is a woman's lifetime exposure to the natural female hormone estrogen. Many types of breast cancer cells contain what have been termed

"estrogen receptors." When estrogen binds to these receptors, the reaction sets in motion a series of chemical and biologic events that allow the cancer cells to thrive and multiply. While estrogen has many beneficial roles in a woman's health, this negative action of promoting breast cancer growth is well documented.

30. Women with higher lifetime exposure to estrogen are thus at greater risk for developing breast cancer. For this reason, the risk of developing the disease is affected by the timing of key hormonal events such as the onset of menstruation, the history of childbearing and the onset of menopause. Non-malignant and pre-cancerous breast lesions are indicators of estrogen activity in the breast and therefore women with these conditions are also at higher risk for developing breast cancer.

31. Treatment options for breast cancer patients changed in the 1970's with the development of a synthetic hormone "antagonist" called tamoxifen, which was shown to have significant "anti-estrogenic" properties. Tamoxifen "antagonizes" (*i.e.* counteracts or neutralizes) the cancer-promoting effects of estrogen in the breast by binding itself to the estrogen receptor in a cancerous cell. The presence of an anti-estrogen such as tamoxifen prevents estrogen from binding to the receptor, which in turn affects tumor growth. Tamoxifen has subsequently been shown to have "estrogen-like" activity in tissues other than the breast, such as the bone. Thus, whether tamoxifen acts like an estrogen or an anti-estrogen depends on the specific tissue.

32. Tamoxifen has since been used, either in addition to or in lieu of more drastic and invasive forms of therapy, to treat both early and advanced-stage breast cancer and to prevent recurrence. Since it was first discovered nearly thirty years ago, tamoxifen has become the most widely prescribed treatment for breast cancer. In fact, tamoxifen is the single most-prescribed drug

in the world for the treatment of cancer of any sort. Tamoxifen is listed as an "Essential Drug" by the World Health Organization and is the standard of comparison in most clinical trials in breast cancer.

C. Nolvadex®

33. On August 20, 1985, Imperial Chemicals Industries, PLC ("ICI" or "Imperial") obtained U.S. Patent 4,536,516 (the "'516 Patent"), covering tamoxifen. ICI's former subsidiary, Zeneca, is the sole producer of tamoxifen under the '516 Patent. In 1993, ICI transferred its rights to the '516 Patent to Zeneca, which became a separate company. Since 1993, Zeneca has marketed tamoxifen under the brand name Nolvadex®. Nolvadex® is one of Zeneca's most successful and widely-prescribed products.

D. Barr files an ANDA

34. In December, 1985, Barr submitted an ANDA requesting FDA approval to market its own generic version of tamoxifen.

35. In September 1987, Barr amended its ANDA to include a Paragraph IV Certification and to challenge the validity of ICI's tamoxifen patent. After amending its ANDA, Barr sent ICI notice that it contended the '516 Patent was invalid. The FDA gave effect to Barr's amended Paragraph IV Certification and Barr became eligible for the potentially 180 day exclusivity incentive under the Hatch-Waxman Act.

E. ICI brings a patent suit against Barr and its patent is found unenforceable

36. After receiving notice of Barr's Paragraph IV Certification, ICI sued Barr for patent infringement in the United States District Court for the Southern District of New York. Also named as a party defendant in that suit was Heumann Pharma, GmbH & Co. ("Heumann"), Barr's supplier

of tamoxifen citrate. Within months of the commencement of the lawsuit, Heumann was dismissed as a defendant, with prejudice, in accordance with the terms of a stipulation. Heumann agreed to be bound by any determination of the validity of the '516 Patent as adjudicated in the action. If the patent was held to be valid, Heumann agreed to not supply tamoxifen in the United States (apart from said supplies necessary solely for the purpose of obtaining approval of the FDA) so long as said patent shall remain valid and in force.

37. On April 20, 1992, following a trial on the merits, Judge Vincent L. Broderick found, by clear and convincing evidence, that ICI's tamoxifen patent was ***unenforceable*** because ICI deliberately, knowingly and fraudulently withheld material information from the Patent and Trademark Office. *Imperial Chem. Ind., PLC v. Barr Lab., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992).

38. On May 21, 1992, Judge Broderick entered a judgment that "Ordered Adjudged and Decreed that United States Patent No. 4,536,516 is unenforceable and that this action is dismissed with prejudice, and with costs to defendant."

F. <u>The Settlement Agreement</u>

39. On June 19, 1992, ICI filed a notice of appeal to bring the case to the United States Court of Appeals for the Federal Circuit. In March 1993, before any substantive review by the Federal Circuit, ICI settled the case with Barr pursuant to a "Confidential Settlement Agreement." The settlement was expressly conditioned on Barr's agreement to abandon its challenge to the validity of the '516 Patent. Barr agreed to abandon its challenge by amending its Paragraph IV certified ANDA to a Paragraph III certified ANDA (*i.e.*, it would not market its generic product until the expiration of the patent). Pursuant to the settlement and as a result of the ANDA amendment, Barr's ANDA was not eligible for approval until after August 20, 2002, the date that ICI's tamoxifen

patent was scheduled to expire. In exchange, ICI/Zeneca agreed to pay Barr ***$21 million***. In addition, paragraph seven of the Confidential Settlement Agreement provided that:

> In addition to the payments set forth in paragraph 6 above, Barr and ZENECA Inc. shall execute the non-exclusive Distributorship and Supply Agreement ... contemporaneously with the execution of this Agreement pursuant to which ZENECA Inc. shall supply or have supplied to Barr generic tamoxifen citrate as identified in Schedule A of the [Distribution and Supply] Agreement which schedule may be amended, from time to time, pursuant to the terms and conditions set forth in paragraph 11 of the [Distribution and Supply] Agreement.

The Confidential Settlement Agreement was expressly conditioned on the Federal Circuit vacating Judge Broderick's judgment finding the '516 Patent unenforceable and invalid.

40. The "Distribution and Supply Agreement," which was executed contemporaneously with the Confidential Settlement Agreement, sets forth the terms pursuant to which Zeneca would supply Barr with Zeneca-manufactured tamoxifen for resale in the United States. Among other things, Barr was required to purchase all of the tamoxifen that it resold in the United States from Zeneca at a price that was a certain percentage of Zeneca's wholesale druggists' cost price. The Distribution and Supply Agreement also provided that:

> Barr may, at its option, terminate this Agreement for any of the following reasons:
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> * * * * * *
>
> (2) In the event that the '516 Patent is held invalid and/or unenforceable in a final, unappealable judgment, Barr may terminate this Agreement immediately, provided, however, that Barr shall pay ZENECA for the inventory of the Product which ZENECA, or its designee, has manufactured or has in the manufacturing process for Product utilizing Barr's intagliation.

Distribution and Supply Agreement ¶ 24(b).

41. Zeneca also entered a settlement with Heumann resolving any disputes between Zeneca and Heumann and the effect of an agreement between Barr and Heumann. Zeneca agreed to pay Heuman $9.5 million at the time of the settlement and further payments over the following ten years totaling $35.9 million. Heumann agreed to release and discharge Zeneca and Barr from any claims arising out of their settlement agreement or the '516 Patent. Like the other agreements, the Zeneca/Heumann Agreement became effective upon entry of an order by the Federal Circuit vacating the judgment entered by Judge Broderick.

42. Adhering to the terms of their settlement agreement, ICI/Zeneca and Barr filed a "Joint Motion To Dismiss The Appeal As Moot And To Vacate The Judgment Below" in the United States Court of Appeals for the Federal Circuit. In the text of that motion, ICI/Zeneca and Barr represented that they had reached a settlement resolving all the issues between the parties and, consequently, under Federal Circuit practice, it was requested that the appeal be dismissed and the district court judgment be vacated. Sidmak Laboratories, Inc. sought leave to file an amicus brief with respect to the motion to dismiss which was opposed by both Zeneca and Barr.

43. In a March 19, 1993 unpublished disposition, the Federal Circuit stated as follows:

> Imperial Chemical Industries PLC (ICI) and Barr Laboratories, Inc. (Barr) jointly move to vacate the July 21, 1992 judgment of the United States District Court for the Southern District of New York and to remand with instructions to the district court to dismiss without prejudice pursuant to Fed.R.Civ. P. 41(a). Generic Drug Manufacturer (Generic) moves for leave to file an amicus curiae brief out of time. ICI opposes. Barr opposes. Generic submits a supplemental exhibit. ***The parties to the district court proceeding have entered into a settlement agreement resolving the entire dispute***. They ask us to vacate and remand in accordance with their agreement and this court's practice. *See Smith International, Inc. v. Hughes Tool Co.*, 839 F.2d 663 (Fed.Cir.1988); *U.S. Philips Corp. v. Windmere Corp.*, 971 F.2d

> 728 (Fed.Cir. 1992), *cert. granted*. Generic seeks to file an amicus brief out of time in order to argue that the court should not vacate the district court's judgment. Generic's motion appears to be a ***belated attempt by a nonparty to interfere with the parties' settlement of a dispute***. Generic's role here is not as a "friend of the court" in the usual sense. Its amicus brief does not address the merits of the appeal. Moreover, the rules governing the filing of amicus briefs contemplate the filing of a brief "within the time allowed the party whose position as to affirmance or reversal the amicus brief will support." Fed. R. App. P. 29. Generic's amicus brief is not only out of time, ***it also does not support the position of either party***.
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> Accordingly, IT IS ORDERED THAT:
> (1) ICI and Barr's joint motion is granted.
> (2) Generic's motion for leave to file an amicus curiae brief is denied.

Imperial Chemical Industries, PLC v. Heumann Pharma GmbH & Co. et al., 991 F.2d 811, 1993 WL 118931 (Fed.Cir. 1993) (unpublished disposition) (emphasis added).

44. On March 23, 1993, Judge Broderick entered a Stipulation of Dismissal and Order which provided as follows:

> Having considered the Order of the United States Court of Appeals for the Federal Circuit, dated March 18, 1993, this case is dismissed without prejudice, each party to bear its own attorneys' fees and costs. So Ordered.

45. Under the terms of the Confidential Settlement Agreement and the Distribution and Supply Agreement, Barr obtained a license to sell Zeneca's tamoxifen as a distributed product. As the *only* "generic" version of tamoxifen available, Barr is able to capture approximately 80% of the market by pricing the product slightly below the price Zeneca charges for Nolvadex®. Zeneca is able to maintain the market share for Nolvadex® without lowering its price. Zeneca is also paid by Barr, of course, for supplying the tamoxifen sold by Barr as a "generic." Zeneca's

tamoxifen—labeled as either Nolvadex® or the "generic" sold by Barr — *is the only tamoxifen on the market*.

G. Subsequent ANDA Filers

46. Within a year of the Federal Circuit's vacatur of Judge Broderick's decision, in August 1994, Pharmachemie, B.V. ("Pharmachemie") submitted an ANDA with a Paragraph III certification for its generic version of tamoxifen. In February, 1996, Pharmachemie amended its ANDA to include a Paragraph IV certification.

47. In January 1996, Mylan Pharmaceuticals, Inc. ("Mylan") submitted an ANDA with a Paragraph IV certification for its generic version of tamoxifen.

48. After Mylan submitted its Paragraph IV ANDA in January 1996, Zeneca sued Mylan for infringement. Because Zeneca brought a patent infringement action against Mylan within 45 days, the 30-month statutory stay of FDA approval was triggered against Mylan and scheduled to expire on July 10, 1998.

49. After Pharmachemie amended its ANDA to reflect a Paragraph IV ANDA, Zeneca sued Pharmachemie for patent infringement in the United States District Court for the District of Massachusetts ("the Massachusetts Court") within 45 days. The 30-month statutory stay was triggered and scheduled to expire in August 1998.

50. The FDA tentatively approved Pharmachemie's ANDA for its generic version of tamoxifen on April 3, 1997.

51. As the end of the 30-month stay for Pharmachemie's ANDA approached, Zeneca filed a motion in the Massachusetts Court to extend the 30-month statutory bar. In an August 10, 1998 ruling, the Massachusetts Court denied that motion. *Zeneca Limited v. Pharmachemie B.V.*, 16 F.

Supp. 2d 112 (D. Mass. 1998).

H. Barr seeks 180 day generic exclusivity period

52. In June 1998, approximately one month before Mylan's and two months before Pharmachemie's 30-month statutory stays were to expire, Barr filed a Petition for Stay with the FDA. The Petition asked the FDA to continue to credit Barr as the first ANDA filer entitled to a 180 day exclusivity period to the exclusion of all other generic makers of tamoxifen. Specifically, Barr's Petition asked the FDA not to approve any ANDA for a generic version of tamoxifen until 180 days after: (1) Barr's first commercial marketing of generic tamoxifen under its ANDA; or (2) the date of a final decision of a court holding the tamoxifen patent to be invalid or not infringed.

53. In response to the Barr's Petition, Janet Woodcock, M.D., Director of the FDA's Center for Drug Evaluation and Research, announced to Barr by letter dated March 2, 1999 ("the March Letter") that the FDA had granted Barr's Petition to preserve its 180 day exclusivity period and to exclude all other generic makers of tamoxifen. The FDA March Letter announced that it was granting Barr's request that the Agency stay the effective date of approval of any ANDA for tamoxifen other than one submitted by Barr, until 180 days after the date of the first commercial marketing of the drug under Barr's ANDA, or the date of a final decision of a court holding the tamoxifen patent to be invalid or not infringed.

54. Pharmachemie and Mylan brought separate actions in the United States District Court for the District of Columbia against Jane E. Henney, M.D., in her official capacity as Commissioner of the United States Food and Drug Administration, and against Donna E. Shalala, in her official capacity as Secretary of the United States Department of Health and Human Services (collectively referred to as the "FDA"). According to Mylan and Pharmachemie, the FDA's March Letter is

inconsistent with the plain language of 21 U.S.C. § 355(j)(5)(B)(iv), with Congress's clear intent and with sound public policy.

55. In a March 31, 2000 ruling, Judge Urbina of the United States District Court for the District of Columbia granted declaratory relief, holding that Barr was no longer eligible for the exclusivity incentive, stating in part as follows:

> In its March Letter, the FDA gives no effect to the Southern District's [of New York] decision, rendered in Barr's favor, which held that Imperial's patent for tamoxifen was invalid. Although the district court's decision was vacated during the pendency of appeal and pursuant to a settlement agreement, the FDA, without explanation, sweepingly ignores the existence of the decision altogether. Page four of the March Letter states: "Barr has settled its patent litigation without a decision of a court finding the patent invalid, not infringed or unenforceable." While subsequent ANDA applicants have challenged the tamoxifen patent, no court decisions have been rendered in those cases either. Thus, according to the FDA's interpretation, Barr's 180 days of marketing exclusivity has not yet been triggered since there is neither a court decision nor a commercial marketing of tamoxifen under Barr's ANDA.
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> * * *
>
> From the plain, comprehensive and inclusive terms of 21 U.S.C. § 355(j)(5)(B)(iii) and (iv), the court discerns clear congressional intent that the draftsmen intended "a decision of a court" to mean all court decisions, whether subsequently vacated, settled, appealed or otherwise mooted. In other words, "to the extent the statute is clear about anything, it clearly forecloses" the FDA's determination to grant Barr's Petition for the reasons announced in the March Letter. If, for example, the agency gives effect to the Southern District decision, then the FDA could interpret the statute to mean that immediate approval applies, and the 180-day exclusivity period will have lapsed. Clause iii, Paragraph I is worth reiterating: "[I]f before the expiration of such period [30 months] the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision." If, however, the FDA ignores the Southern District decision, i.e., elects to treat the Southern District decision as though no decision occurred at all, then the interpretation

> violates the policy of Hatch-Waxman because the Exclusivity Incentive would never be triggered.
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> * * *
>
> The Imperial-Barr Settlement, perhaps inadvertently, delays the approval of subsequent ANDA's by chilling the market incentive. The FDA's March Letter ratifies this outcome. There is no support in the record for the assertion that this was Congress' intent in passing the Hatch-Waxman Amendments. For all these reasons, following the plain language of the text and attributing ordinary meaning to the words used, this court determines that Clause iii and Clause iv of 21 U.S.C. § 355(j)(5)(B) unambiguously apply to the Southern District decision that invalidated Imperial's tamoxifen patent, regardless of whether that decision was later vacated. Title 21 U.S.C. § 355(j)(5)(B)(iii) and (iv) are unambiguous and exceedingly precise and, moreover, intend "a decision of the court" to cover a district court decision subsequently appealed and vacated pursuant to a settlement during the pendency of the appeal. To conclude otherwise would be contrary to the plain meaning and purpose of these provisions.

Mylan Pharmaceuticals, Inc. v. Henney, 94 F. Supp.2d 36, 49-54 (D.D.C. 2000).

I. The Effect of the Confidential Settlement Agreement and the Distribution and Supply Agreement

56. Contrary to the purpose of the Hatch-Waxman Act, the Confidential Settlement Agreement and the Distribution and Supply Agreement have enabled Zeneca and Barr to: (i) revive a patent that Barr had established was invalid and unenforceable; (ii) allocate the entire United States market for tamoxifen to one manufacturer–Zeneca; (iii) share the monopoly profits of Zeneca's tamoxifen; (iv) avoid price competition and maintain artificially inflated market price for Nolvadex® and its Zeneca-manufactured "generic;" and (v) exclude competition from other generic manufacturers.

57. On September 30, 1999, USA Today reported that The Federal Trade Commission was investigating anticompetitive deals between drugmakers. Among the deals under investigation by the Justice Department, according to the article, was:

> Zeneca Pharmaceuticals' deal with Barr Laboratories involving the generic equivalent of the breast cancer drug tamoxifen. Zeneca settled a 1993 patent-infringement lawsuit against Barr by paying Barr $21 million and giving it a nonexclusive deal to distribute a generic form of tamoxifen manufactured by Zeneca. Barr now makes about $30 million a year from the deal. The Justice Department is not expected to bring a case, but the probe remains open.

"FTC Looks At Deals By Drugmakers," *USA Today*, Sept. 30, 1999.

58. In response to the *USA Today* article, Barr issued a press release on September 30, 1999 that stated as follows:

> Barr Laboratories, Inc. (NYSE:BRL) said it is encouraged by a report in USA Today that the Department of Justice is not expected to bring a case regarding its Tamoxifen patent challenge settlement. The Company today reiterated that it s Tamoxifen agreement is pro-consumer and pro-competitive and has saved breast cancer patients millions of dollars.
>
> "There is clearly more competition today than before Barr challenged the Tamoxifen patents. Without this agreement, there would currently be no competition for the brand product," said Bruce L. Downey, Barr's Chairman, President and CEO. "The millions of dollars in savings clearly show our agreement has been pro-consumer. Eight-out-of-ten women who take Tamoxifen today use our lower cost version, eight years earlier than they would have if we had pursued our challenge and failed." The Company distributes its product to drug stores, distributors and wholesalers at approximately 15% less than the brand price.

59. Despite Barr's attempt to "spin" the Confidential Settlement Agreement and the Distribution and Supply Agreement as pro-consumer and pro-competitive, the agreements are plainly *pro*-Barr and Zeneca and *anti*-competitive. If the appeal of the patent suit against Barr had run its

course and resulted in an affirmance of Judge Broderick's finding of invalidity, Zeneca's patent would have been removed from the FDA Orange Book and any applicable 180-day exclusivity period would have begun to run. As a result of the Confidential Settlement Agreement and the Distribution and Supply Agreement avoiding such an outcome, Zeneca's '516 Patent remains listed in the Orange Book, with both Zeneca and Barr sharing the benefits. Instead of the 180-day period as the exclusive generic distributor Barr would have received as an "incentive" under the Hatch-Waxman Act, the Confidential Settlement Agreement and Distribution and Supply Agreement have left Barr as the exclusive "generic" distributor (of Zeneca's product) for *more than six years and counting*.

60. Indeed, on May 2, 2000 Barr stated that:

> Tamoxifen sales increased 9% from $83,929 to $91,361 [in thousands]. The increase was due to higher prices and an expansion in the use of Tamoxifen. In October 1998, Tamoxifen was approved to reduce the incidence of breast cancer in women at high risk of developing the disease. Tamoxifen is a patent protected product manufactured for the Company by the Innovator. *Currently, Tamoxifen only competes against the Innovator's product, which is sold under the brand name.*

Management's Discussion and Analysis of Financial Condition and Results of Operation, May 2, 2000 (emphasis added).

61. As Barr states on its web-page, "[g]eneric pharmaceuticals can cost 30-80% less than the equivalent, branded product." The reason, of course, is that consumers benefit from competition among generic manufacturers vying for market share. If there is only one generic on the market, it can capture the bulk of the market merely by pricing below the brand-name. Indeed, the Hatch-Waxman Act intends to reward the first ANDA filer with a 180-day exclusivity period so that it can

recoup the cost of challenging the pioneer manufacturer's patent before the market is opened to full competition. The Confidential Settlement Agreement and the Distribution and Supply Agreement enables both Zeneca and Barr to maintain prices for tamoxifen at artificially inflated levels for both the brand-name and the generic.

62. A review of the prices charged for tamoxifen demonstrates the impact of the Confidential Settlement Agreement and Distribution and Supply Agreement. On October 4, 2000, for example, drugstore.com listed the following prices for tamoxifen:

Nolvadex	60 tablets	180 tablets
Tablets	10 MG$100.80	$290.91
Tablets	20 MG$197.23	$581.82
Generic (Tamoxifen Citrate)		
Tablets	10 MG$95.76	$276.36
Tablets	20 MG$187.36	$552.73

Rather than a 30-80% discount (or even the 15% discount cited by Barr), each generic price listed is approximately ***5%*** less than the brand-name price. Insulated from all generic competition by the Confidential Settlement Agreement and Distribution and Supply Agreement, Zeneca and Barr are therefore able to charge artificially inflated prices for tamoxifen sold as either Nolvadex® or the sole source generic. Although Barr markets approximately seventy generic drugs, Barr's 10-K for the Fiscal Year ended June 30, 2000, reports that tamoxifen accounted for ***66%*** of Barr's yearly product sales.

CLASS ACTION ALLEGATIONS

63. Plaintiffs bring this class action pursuant to Fed.R.Civ.P. 23 on behalf of themselves and on behalf of all similarly situated consumers in the United States and its territories (for Count I and Count IV) or in Michigan (for Count II) or in the Indirect Purchaser States (for Count III) who

purchased tamoxifen for personal or family use (the "Class") during the period November 9, 1996 through such time in the future as Defendants' illegal conduct, as alleged herein, has ceased (the "Class Period"). Excluded from the Class are all Defendants and their respective subsidiaries and affiliates, all governmental entities and all persons or entities that purchased tamoxifen directly from any of the Defendants.

64. The members of the Class are so numerous that joinder of all members is impracticable. Tamoxifen purchasers number in the millions nationally and there are, at a minimum, thousands of tamoxifen purchasers in each State.

65. Defendants' illegal, anticompetitive and inequitable methods, acts and trade practices have targeted and affected all members of the Class in a similar manner, *i.e.*, they have been deprived of a competitive market and overpaying for tamoxifen due to the absence of true generic versions of tamoxifen in the marketplace, and will continue to pay supra-competitive prices until true generic versions of the drug are available. Among the questions of law and fact common to the Class are:

(a) Whether, under common principles of antitrust and trade practice law, Defendants' methods, practices and acts, as alleged herein, including, but not limited to, the Agreements, violated federal and state antitrust laws;

(b) Whether Defendants' acts, contracts, combination and conspiracy restrained competition for the sale of tamoxifen and its generic bioequivalents and prevented or delayed introduction of generic versions of tamoxifen in the United States;

(c) Whether, under common principles of antitrust law, the "Distribution and Supply Agreement" and the "Confidential Settlement Agreement" constitute a *per se* violation of federal and state antitrust laws or are properly analyzed under the "Rule of Reason" standard;

(d) Whether, if a "Rule of Reason" analysis is appropriate, under common principles of antitrust law, Zeneca had monopoly power over the relevant markets for tamoxifen

and its generic bioequivalents;

(e) Whether, if a "Rule of Reason" analysis is appropriate, under common principles of antitrust law, the United States market for tamoxifen and its generic bioequivalents is a relevant market, judged from the viewpoint of the Class;

(f) Whether, under common principles of federal and state antitrust law, Plaintiffs and the Class suffered antitrust injury;

(g) The amount by which Defendants' illegal, anticompetitive, inequitable and unfair trade practices have inflated the prices paid by members of the Class for tamoxifen over the amounts they would have paid in a competitive market unaffected by Defendants' illegal acts; and

(h) Whether, under common principles of unjust enrichment, Defendants unjustly enriched themselves to the detriment of Plaintiffs and the Class, entitling Plaintiffs and the Class to disgorgement of all profits resulting therefrom, including all funds paid by Zeneca to Barr and all overcharges and injuries incurred due to Defendants' conduct.

66. Plaintiffs' claims are typical of those of the Class they represents because they and all of the Class members were injured and continue to be injured in the same manner by Defendants' illegal and unfair methods, acts and practices and wrongful conduct complained of herein, *i.e.*, they have paid and continue to pay supra-competitive prices, until the market for generic bioequivalents is truly competitive.

67. Plaintiffs will fully and adequately protect the interests of all members of the Class. Plaintiffs have retained counsel who are experienced in class action and antitrust litigation. Plaintiffs have no interests which are adverse to or in conflict with other members of the Class.

68. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members.

69. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty to be encountered in the

management of this action that would preclude its maintenance as a class action.

COUNT I

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTIONS 1 AND 2 OF THE SHERMAN ACT

(Asserted by Plaintiffs and the Class Against All Defendants)

70. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

71. Section 1 of the Sherman Act provides that:

> Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal.

15 U.S.C. § 1.

72. Section 2 of the Sherman Act provides in pertinent part that:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons to monopolize any part of trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony....

15 U.S.C. § 2.

73. Defendants' contract, combination or conspiracy has included concerted action and undertakings among Defendants with the purpose and effect to: (a) allocate the market for sales of tamoxifen (and for generic bioequivalents of tamoxifen) in the United States to Zeneca, with Barr selling the product manufactured by Zeneca as generic; (b) fix, raise, maintain and stabilize the price of tamoxifen; and (c) preclude Plaintiffs and the Class from the opportunity to purchase other, less expensive, generic versions of tamoxifen.

74. For the purpose of formulating and effectuating their contract, combination or conspiracy, Defendants performed the various acts, as alleged herein, including the following:

(a) entering into an illegal agreement by which Barr agreed not to sell its generic tamoxifen in United States commerce in exchange for an initial payment of $21 million and a license to sell Zeneca's tamoxifen as a generic;

(b) depriving consumers of the ability to purchase tamoxifen, or its generic equivalent, at a competitive price.

75. The acts done by each of the Defendants as part of, and in furtherance of, their contract, combination or conspiracy were authorized, ordered or done by their officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

76. Defendants' illegal contract, combination or conspiracy to prevent the introduction into the United States marketplace of any generic version of tamoxifen resulted in Plaintiffs and the Class paying more than they would have paid for tamoxifen, absent the Defendants' illegal conduct.

77. Defendants' contract, combination or conspiracy is a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

78. In the alternative, Defendants' contract, combination or conspiracy violates Section 1 of the Sherman Act, 15 U.S.C. § 1, under the Rule of Reason, because its purpose and effect was to unreasonably restrain competition in the Relevant Market.

79. The Agreements are and were purely private agreements among Defendants. These purely private Agreements of which Plaintiffs complain unlawfully restrained trade.

80. The vacatur of the findings of patent invalidity furthered Defendants' contract, combination and conspiracy in restraint of trade. Barr acknowledged the validity and enforceability of the '516 Patent despite the fact that Barr had established by clear and convincing evidence that

the patent was invalid. The vacatur was the result of private negotiations among Defendants, rather than any judicial determination regarding the validity or enforceability of the patent. Neither the Southern District of New York nor the Federal Circuit actively scrutinized or supervised the terms of the Confidential Settlement Agreement and the Distribution and Supply Agreement.

81. Defendants have undertaken the foregoing unlawful courses of conduct for the following purposes and with the following effects:

(a) The market for tamoxifen has been allocated to Zeneca's product, with Barr licensed to sell the product as a generic in exchange for its agreement not to market its own product which, after 180 days, would allow other generic manufacturers to enter the market;

(b) Prices for tamoxifen have been fixed, raised, maintained or stabilized at artificially high and non-competitive levels;

(c) Consumers of tamoxifen have been deprived of the benefits of free and open competition in their purchases; and

(d) Competition in the production and sale of tamoxifen and its generic bioequivalents has been restrained, suppressed and eliminated.

82. As a result of the illegal conduct of Defendants, Plaintiffs and the Class continue to pay artificially inflated prices for tamoxifen and to be deprived of the ability to purchase other, less expensive, generic versions of the drug. The prices charged by Defendants for tamoxifen are substantially greater than the prices that consumers would pay absent the illegal agreements, combination or conspiracy alleged herein. As a result of Defendants conduct alleged herein, Plaintiffs and members of the Class continue to sustain substantial losses and damage to their business and property.

83. Plaintiffs and the Class, therefore, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaration that the Confidential Settlement

Agreement and the Distribution and Supply Agreement are a *per se* violation Section 1 of the Sherman Act.

84. Section 16 of the Clayton Act, authorizing suits for injunctive relief, provides in part:

> Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties, against threatened loss or damage by a violation of the antitrust laws, ... when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity.

15 U.S.C. § 26. Plaintiffs and the Class seek the issuance of an injunction prohibiting Defendants' continued compliance with the unlawful terms of the Agreements.

85. Plaintiffs and the Class have no adequate remedy at law.

COUNT II

FOR DAMAGES, INJUNCTIVE AND DECLARATORY RELIEF UNDER THE ANTITRUST ACT

(Asserted by Plaintiffs And the Class Against All Defendants)

86. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

87. The Agreement is an agreement between horizontal competitors in the same chain of distribution, which has the effect of allocating market share and restraining trade. Such an allocation is a classic example of a contract, combination or conspiracy in restraint of trade and commerce which is *per se* prohibited under the Antitrust Act.

88. With the specific intent to prevent competition from producers of generic tamoxifen and thereby maintain the Zeneca's monopoly over the market for tamoxifen and its generic

bioequivalents and to create a perpetual monopoly for Zeneca in the Relevant Market, Defendants, supposed horizontal competitors, have engaged in a combination in the form of a trust and a conspiracy, as evidenced by the Confidential Settlement Agreement and Distribution and the Supply Agreement, and have thereby succeeded in restraining trade in the Relevant Market for tamoxifen.

89. Defendants' unlawful contracts, agreements, arrangements, and combinations in restraint of trade or commerce and attempts to monopolize, conspiracies to monopolize and monopolization of the Relevant Market alleged herein, violate the Antitrust Act.

90. Section 2 of the Antitrust Act, MCL §445.772, provides:

> Sec. 2. A contract, combination, or conspiracy between 2 or more persons in restraint of, or to monopolize, trade or commerce in a relevant market is unlawful.

91. Section 3 of the Antitrust Act, MCL §445.773, provides:

> Sec. 3. The establishment, maintenance, or use of a monopoly, or any attempt to establish a monopoly, of trade or commerce in a relevant market by any person, for the purpose of excluding or limiting competition or controlling, fixing, or maintaining prices, is unlawful.

92. Plaintiffs and the Class are empowered by MCL §445.778(2) to commence a private action for up to three times their actual damages, and for costs and reasonable attorney fees, due to the injuries they have suffered and continue to suffer as a result of Defendants' violations of the Antitrust Act. MCL §445.778(2) provides:

> Any other person threatened with injury or injured directly or indirectly in his or her business or property by a violation of this act may bring action for appropriate injunctive or other equitable relief against immediate irreparable harm, actual damages sustained by reason of a violation of the act, and, as determined by the court, interest on the damages from the date of the complaint, taxable costs, and reasonable attorney's fees. If the trier of fact finds that the violation is flagrant, it may increase recovery to an amount not in excess of 3 times the actual

damages sustained by reason of a violation of this act.

93. Plaintiffs and the Class are "persons" within the meaning of the Antitrust Act as described in MCL §445.771.

94. The Agreements violate the Antitrust Act and, therefore, are void and unenforceable.

95. Plaintiffs and the Class seek three times their actual damages as permitted by law for their injuries caused by Defendants' flagrant violations of the Antitrust Act.

COUNT III

FOR DAMAGES, INJUNCTIVE AND DECLARATORY RELIEF UNDER THE ANTITRUST ACT AND CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

(Asserted By Plaintiffs And Tamoxifen Consumers Residing In The Indirect Purchaser States Against All Defendants)

96. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

97. Defendants' unlawful contracts, agreements, arrangements, and combinations in restraint of trade or commerce alleged herein and attempts to monopolize, conspiracies to monopolize and monopolization of the Relevant Market alleged herein, violate the Indirect Purchaser States' antitrust and/or consumer protection laws as follows:

(a) The aforementioned practices by Defendants were and are in violation of Arizona Revised Statutes § 44-1408B;

(b) The aforementioned practices by Defendants were and are in violation of the Cartwright Act, California Business and Professions Code Sections 16700 et seq., and the California Unfair Competition Act, California Business and Professions Code Sections 17200 *et seq.*;

(c) The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act of 1980, D.C. Code § 28-4501 *et seq.* (1996 Rpl.);

(d) The aforementioned practices by Defendants were and are in violation of Chapter 501, Part II, Florida Statutes (the Florida Deceptive and Unfair Trade Practices Act);

(e) The aforementioned practices by Defendants were and are in violation of Kansas Statutes Annotated §§ 50-801(b) and 50-101 *et seq.*;

(f) The aforementioned practices by Defendants were and are in violation of Louisiana Revised Statutes § 51:137;

(g) The aforementioned practices by Defendants were and are in violation of Maine Revised Statutes Annotated, 10 M.R.S.A. § 1101 *et seq.*, and Maine's Unfair Trade Practices Act, 5 M.R.S.A. § 205-A *et seq.*;

(h) The aforementioned practices by Defendants were and are in violation of Massachusetts Ann. Laws, Ch. 93A *et seq.*, the Massachusetts Consumer Protection Act;

(i) The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, MCL 445.771 *et seq.*, and the Michigan Consumer Protection Act, MCL § 445.901 *et seq.*;

(j) The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Act of 1961, Minn. Stat. §§ 325D.49-325D.66 (1998);

(k) The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1 to § 57-1-5 (1998);

(l) The aforementioned practices by Defendants were and are in violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-1 *et seq.*;

(m)The afore-mentioned practices by Defendants were and are in violation of the Donnelly Act, New York General Business Law § 340 et seq.;

(n) The aforementioned practices by Defendants were and are in violation of North Carolina Gen. Stat. §§ 75-1, -1.1, -2 and -2.2;

(o) The aforementioned practices by Defendants were and are in violation of North Dakota Cent. Code § 51-08.1-08;

(p) The aforementioned practices by Defendants were and are in violation of South Dakota antitrust law SDCL ch. 37-1 *et seq.*;

(q) The aforementioned practices by Defendants were and are in violation of Tenn. Code Ann. § 47-25-101 *et seq.*, and in violation of Tenn. Code Ann. § 47-18-101 *et seq.* (the Tennessee Consumer Protection Act of 1977);

(r) The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W. Va. Code §47-18-1 *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101 *et seq.*; and

(s) The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act. § 133.01 *et seq.*, Wis. Stats.

98. The Confidential Settlement Agreement and the Distribution and Supply Agreement violate the statutes referenced above and, therefore, are void and unenforceable.

99. Plaintiffs and the Class seeks damages and treble damages as permitted by law for their injuries caused by these flagrant violations pursuant to these statutes.

COUNT IV

FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS

(Asserted by Plaintiffs and the Class Against All Defendants)

100. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

101. Zeneca has benefited from the overcharges it has been able to levy for tamoxifen resulting from acts alleged in this Complaint, and resulting in overpayments by Plaintiffs and the Class for tamoxifen. Barr has also benefitted from its sales of Zeneca-manufactured tamoxifen at supra-competitive prices.

102. Defendants have unlawfully and inequitably benefitted from the acts alleged in this Complaint to the extent of the payments they have received pursuant to the Confidential Settlement Agreement and the Distribution and Supply Agreement. The funds for such payments are traceable to Plaintiffs' and the Class' overpayments for tamoxifen.

103. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

104. The economic benefit of overcharges and monopoly profits obtained by supra-competitive prices is a direct and proximate cause of Defendants' anti-competitive behavior restricting competition as set forth above.

105. The benefit held by the Defendants rightfully belongs to Plaintiffs and the Class, as Plaintiffs and the Class paid these anti-competitive sums to Defendants during and before the Class Period, when Defendants used anti-competitive measures to block generic entry into the market.

106. It would be inequitable for Defendants to be permitted to retain any of the proceeds of the Confidential Settlement Agreement and Distribution and Supply Agreement.

107. It would be inequitable for the Zeneca or Barr to be permitted to retain any of the Plaintiffs' and the Class' overpayments for tamoxifen derived from their unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

108. Defendants should be compelled to disgorge into a common fund for the benefit of Plaintiffs and the Class, all unlawful or inequitable proceeds received by them as a result of the Confidential Settlement Agreement and Distribution and Supply Agreement.

109. A constructive trust should be imposed upon all unlawful sums retained by Defendants and traceable to Plaintiffs and the Class.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class pray for judgment against all Defendants, jointly and severally, as follows:

1. certifying this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, certifying Plaintiffs as Class representatives, and designating their counsel as Class counsel;

2. declaring that the Confidential Settlement Agreement and the Distribution and Supply Agreement are *per se* violations of §1 of the Sherman Act, 15 U.S.C. § 1, the Antitrust Act and the antitrust and/or consumer protection laws in the Indirect Purchaser States;

3. declaring that the Confidential Settlement Agreement and the Distribution and Supply Agreement are violations of § 2 of the Sherman Act, 15 U.S.C. § 2, the Antitrust Act and the antitrust and/or consumer protection laws in the Indirect Purchaser States;

4. enjoining and restraining Defendants' continuing violations of §§ 1 and 2 of the Sherman Act, pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, and pursuant to the Antitrust Act and the antitrust and/or consumer protection laws in the Indirect Purchaser States;

5. granting Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution and the creation of a constructive trust to remedy Defendants' unjust enrichment;

6. awarding Plaintiffs and the Class three times their actual damages, jointly and severally, for Defendants' flagrant violations of the Antitrust Act and the antitrust and/or consumer protection laws in the Indirect Purchaser States, where permitted, in an amount to be determined at trial;

7. granting Plaintiffs and the Class the costs of prosecuting this action, together with interest and reasonable attorneys' fees and costs; and

8. granting such other relief as this Court may deem just and proper under the circumstances.

JURY DEMAND

To the full extent available, Plaintiffs demand a trial by jury.

DATED: November 9, 2000

Respectfully Submitted,

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